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09/505,598	02/16/2000	Arnold M. Escano	ENDOV-48232	6592

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EXAMINER

BLANCO, JAVIER G

ART UNIT PAPER NUMBER

3738

DATE MAILED: 09/26/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/505,598

Applicant(s)

ESCANO ET AL.

Examiner

Javier G. Blanco

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Drawings

1. This application has been filed with informal drawings, which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 25-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Regarding claim 25, amended limitation “wherein one of the first and second release wires operate to maintain one of the second and third anchoring mechanisms in an unexpanded condition” (see lines 14-15) renders the claim vague and indefinite:

(i) If the first release wire is “releasably attached to the ipsilateral inferior extremity such that the second anchoring mechanism maintains an unexpanded condition” (see lines 10-11), and

(ii) If the second release wire is “releasably attached to the contralateral inferior extremity such that the third anchoring mechanism maintains an unexpanded condition” (see lines 10-11), then

(iii) The language of lines 14-15 (“wherein one of the first and second release wires operate to maintain one of the second and third anchoring mechanisms in an unexpanded

Art Unit: 3738

condition”) gives the impression that the first and second release wires are interchangeably connected to either the second or third anchoring mechanisms.

b. Regarding claim 37:

(i) Newly added limitation “one of the first and second release wires” (see line 9) lacks antecedent basis, and

(ii) Newly added limitation “one of the second and third anchoring mechanisms” (see lines 9-10) lacks antecedent basis.

c. Regarding claim 38, amended limitation “configuring one of the first and second release wires to maintain one of the second and third anchoring mechanisms in an unexpanded condition” (see lines 13-14) renders the claim vague and indefinite:

(i) If the first release wire is “releasably fastened to the first expandable anchoring mechanism such that the first expandable anchoring mechanism is maintained in an unexpanded condition” (see lines 6-8), and

(ii) If the second release wire is “releasably fastened to the second expandable anchoring mechanism such that the second expandable anchoring mechanism is maintained in an unexpanded condition” (see lines 10-11), then

(iii) The language of lines 13-14 (“configuring one of the first and second release wires to maintain one of the second and third anchoring mechanisms in an unexpanded condition”) gives the impression that the first and second release wires are interchangeably connected to either the second or third anchoring mechanisms,

(iv) The first release wire is releasably fastened to the first expandable anchoring mechanism, not to the second or third expandable anchoring mechanisms.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 25-36 and 38-40 are rejected, as best understood, under 35 U.S.C. 102(b) as being clearly anticipated by Quiachon et al. (US 5,628,783). Quiachon et al. disclose an apparatus and method for intraluminally delivering or deploying a bifurcated graft proximate the abdominal aortic bifurcation. The apparatus and method meet all the limitation of claims 25-36 and 38-40 (see whole text and Figures 1-36). As seen in Figures 1, 7, and 27, the guiding tube assembly 205 comprises a release wire that is operated (= used) to control the contralateral capsule 202 in order to maintain an anchoring mechanism in an unexpanded condition and to deploy it when the contralateral tubular leg is properly positioned (see also column 20, lines 39-47).

6. Claim 37 is rejected, as best understood, under 35 U.S.C. 102(b) as being clearly anticipated by Quiachon et al. (US 5,628,783). Quiachon et al. disclose an apparatus and method for intraluminally delivering or deploying a bifurcated graft proximate the abdominal aortic bifurcation. The apparatus and method meet all the limitation of claim 37 (see whole text and Figures 1-36).

7. Claims 1-31, 33, and 36-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Piplani et al. (US 5,489,295). Piplani et al. disclose an apparatus and method for intraluminally deploying a bifurcated graft 20 into a lumen formed by a wall proximate a vascular bifurcation

Art Unit: 3738

having an aneurysm. The bifurcated graft 20 comprises main cylindrical body 112, first tubular leg 116, and second tubular leg 117. A main catheter or capsule catheter 26, having a diameter ranging from 6-9 mm, houses the bifurcated graft, a set of positioning mechanisms, and a set of attaching mechanisms (see Abstract; column 2, lines 7-46; column 3, lines 7-9; Figure 1). The attaching mechanisms include expandable anchor or spring attachment means 126, 127, and 163 (having hook-like vessel engaging elements 141) attached to main cylindrical body 112, to first tubular leg 116, and to second tubular leg 117 respectively (see column 5, lines 29-67; column 10, lines 21-35; Figures 4, 8, and 17). The attaching mechanisms also include a balloon catheter assembly 71 capable of expanding the expandable spring attachment means (see column 2, lines 19-34; Figures 1 and 5). The attaching mechanisms further include a stabilization wire 89 and a stabilization button 106 carried by the tubular member or catheter shaft 72 to constrict the expandable anchor in an unexpanded condition (see column 9, lines 2-10; Figure 5). The set of positioning mechanisms includes a main guidewire 91 configured as a stiffened rod (see Figure 1). The set of positioning mechanisms of second tubular leg 117 includes a guidewire 196 that could be removably attached to second tubular leg 117 (see column 10, lines 9-26; Figure 18), secondary catheters (capsule catheter 161 and balloon catheter 162) encompassing at least a portion of the second tubular leg 117, and an expandable spring mechanism 163 at least partially encompassed by the secondary catheter (see column 10, lines 9-35; Figure 6). The attaching mechanism of secondary catheter includes a stabilization button 216 carried by the tubular member 176 to constrict the expandable anchor 163 in an unexpanded condition (see column 10, lines 21-35; Figure 6).

Response to Arguments

8. Regarding 102(b) rejection over Quiachon et al., Applicant's arguments filed July 10, 2003 have been fully considered but they are not persuasive:

a. Applicants argue that Quiachon et al. does not disclose “an apparatus or a method involving one of a first and a second release wire that operates to maintain a second or third anchoring mechanism in an unexpanded condition”. Examiner respectfully disagrees. Quiachon et al. disclose the combination of contralateral capsule 202 with guiding tube assembly (i.e., release wires: distal guiding tube 206 and proximal guiding tube 213) configured to retain and deploy the contralateral attachment system (see column 20, lines 39-47; column 21, lines 20-23; see entire document). Quiachon et al. also disclose ipsilateral locking wire (i.e., release wire) configured to retain and deploy the ipsilateral attachment system (see column 10, lines 53-64; column 26, lines 23-39; see entire document).

9. Regarding 102(b) rejection over Piplani et al., Applicant's arguments filed July 10, 2003 have been fully considered but they are not persuasive:

a. Claim 1 requires, among other things, “the set of attaching mechanisms being sutured to the bifurcated graft”. This claim limitation is met in Figure 4, wherein the attaching mechanisms are attached to the graft by suture material 144. Piplani et al. disclose the subject matter of suturing attaching mechanisms to the bifurcated graft (see column 5, lines 63-67; column 6, lines 1-2).

b. Regarding claim 25, Applicant argues that Piplani et al. does not disclose “one or more of the first and second release wires themselves operating to maintain an anchoring mechanism in an unexpanded condition”. Examiner respectfully disagrees. From 102(b) rejection above: “The attaching mechanisms further include a stabilization wire 89 (= release wire) and a stabilization

Art Unit: 3738

button 106 carried by the tubular member or catheter shaft 72 to constrict the expandable anchor in an unexpanded condition (see column 9, lines 2-10; Figure 5). The set of positioning mechanisms includes a main guidewire 91 configured as a stiffened rod (see Figure 1). The set of positioning mechanisms of second tubular leg 117 includes a guidewire 196 that could be removably attached to second tubular leg 117 (see column 10, lines 9-26; Figure 18), secondary catheters (capsule catheter 161 and balloon catheter 162) encompassing at least a portion of the second tubular leg 117, and an expandable spring mechanism 163 at least partially encompassed by the secondary catheter (see column 10, lines 9-35; Figure 6). The attaching mechanism of secondary catheter includes a stabilization button 216 carried by the tubular member 176 to constrict the expandable anchor 163 in an unexpanded condition (see column 10, lines 21-35; Figure 6)."

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

Art Unit: 3738

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 703-605-4259. The examiner can normally be reached on M-F (7:00 a.m.-4:30 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB

September 19, 2003



David H. Willse
Primary Examiner